Remarks

Claims 23-38 are pending in the present application. The claims have been rejected under 35 U.S.C. §103 for alleged obviousness. In particular, the rejection alleges that the claims are unpatentable over United States Patent No. 5,403,586 (hereinafter, "the '586 patent") as is evidenced by WO 96/11711 ("the '711 publication") in view of United States Patent No. 6,528,058 ("the '058 patent") and WO 99/02180 ("the '180 publication"). The rejection has been carefully considered, but is most respectfully traversed.

The presently claimed invention is, inter alia, directed to adjuvant compositions that comprise an ionic polysaccharide and an immunostimulating complex (or "iscom"), wherein the mass ratio of the ionic polysaccharide to the iscom is in the range of 50 to 300. The present invention further claims immunogenic compositions comprising an immunogen, such as, for example, LHRH, or LHRH conjugates, and the above-described adjuvant composition.

In the rejection, it is urged that: (1) the '586 patent teaches vaccine compositions comprising LHRH and a saponin adjuvant combined with DEAE-dextran; (2) the '058 patent teaches the claimed molar ratio of saponin component to polycationic polyeletrolyte (e.g., DEAE-dextran); and (3) the '180 publication teaches immunogenic LHRH-diptheria toxiod ("DT") conjugates for use in fertility and/or reproduction control. Thus, the rejection alleges that "one of ordinary skill in the art would have been motivated to combine the molar ratio . . . taught by the '058 patent to the LHRH-DT taught by the '180 publication to the LHRH vaccine composition comprising saponin and DEAE-dextran taught by the '586 patent . . . ." (Office Action, dated November 22, 2005, at page 3). For the reasons that follow, this rejection is respectfully traversed.

In particular, in the present situation, the rejection is based in large part on the teachings of the '180 publication. However, Applicant respectfully submits that any reliance on such publication is improper because the '180 publication either does not qualify as prior art or, alternatively, cannot preclude patentability under Section 103 because it, along with the present application, were co-owned by the same person – i.e., CSL Limited – at the time the claimed invention was made (and continue to be co-owned by the present owner, Pfizer, Inc.). Thus, under 35 U.S.C. §103(c), the '180 publication cannot be used to preclude patentability. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

In so far as the '586 and '058 patents are concerned, one of ordinary skill in the art would find no motivation to combine their respective teachings; moreover, even if the motivation to combine could be found, the resulting combination would nonetheless fail to render the present invention obvious. In this regard, Applicant respectfully wishes to direct

the Examiner's attention to the basic criteria for establishing a prima facie case of obviousness as set forth in the MPEP §2143. First, there must be some suggestion or motivation to combine the teachings of the individual references cited. Second, there must be a reasonable expectation that such combination would be successful. Finally, the prior art references, when combined, must teach or suggest each of the claimed limitations. It is respectfully submitted that at least two of the above three requirements have not been met here.

In particular, the '586 patent relates to the preparation of LHRH fusion proteins - not LHRH conjugates. Indeed, the '586 patent specifically teaches away from the preparation of conjugates: "Chemical conjugation is, however, difficult to control and often results in a heterogeneous and ill-defined product." ('586 patent at col. 2, lines 18-19). In contrast to conjugation, the '586 patent teaches the fusion of LHRH analogue coding sequences to particular insertion sites in TraTp coding sequences.

The '058 patent is directed to adjuvant compositions for stimulating an immune response to an antigenic substance. The '058 patent, however, makes no reference to fusion proteins; instead, it describes the antigenic substances as chemical conjugates. Accordingly, because the '586 patent teaches away from the use of such conjugates, one of ordinary skill in the art would find no motivation to combine its teachings with those of the '058 patent. Thus, Applicant respectfully requests that the rejection be withdrawn.

In addition, even, assuming for the sake of argument only, that some motivation could be found to combine the teachings of the '586 and '058 patents, the resulting combination would not teach or suggest each and every limitation of the presently clamed invention. In this regard, the '058 patent makes no reference to LHRH; and neither patent makes any reference to LHRH conjugates in general, DT, or conjugates of DT and LHRH. Likewise, the '711 publication, which is relied upon in the rejection to establish that saponins in the form of iscoms can be used as adjuvants, contains no disclosure or suggestion concerning LHRH, DT, or conjugates of LHRH and DT. Consequently, any combination of the references cited would – at best - result in vaccines comprising LHRH-TraTp fusion proteins and saponin (or iscom) adjuvants of the '058 patent (or '711 publication). Thus, because such combination would not teach or suggest the claimed LHRH-DT conjugates, Applicant respectfully requests that the rejection be withdrawn.

Applicant respectfully requests that the foregoing remarks be entered and made of record in the present application. In addition, applicant respectfully requests consideration of the pending claims and early allowance of the application. No additional fee is believed due.

However, if any fee is due, the Examiner is authorized to charge the fee to Applicants' Deposit Account No. 16-1445.

Respectfully submitted,

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